

REMARKS

To facilitate clear and expeditious examination, Applicants have amended the application as follows:

Claims 1, 4 and 8-9 have been amended.

Claims 3, 5-7, 10-30 have been cancelled.

Claims 31-39 have been added.

The amendments to the claims do not add new matter. In claims 1, 4 and 8-9, the Applicants have corrected the use of the term “xenograft” (a noun) to its proper adjectival form “xenogenic.” Support for the term “xenogenic” as a modifier of the term “graft” is found throughout the specification, including at page 3, lines 6-7 (“... a BTB obtained from xenogenic sources.”). The amendment to claims 1, which recites the limitation of a tendon attached “by a naturally occurring tendon-to-bone attachment” on the bone block, is supported throughout the specification, including at page 2, lines 19-21 (“excising a first bone plug having attached thereto a tendon or ligament; and excising a second bone plug having attached thereto a tendon or ligament”), by Examples 1 and 2, and FIG. 9A-9C (showing an excised porcine BTB). Claim 1, which also recites that the first and second bone blocks have “a groove along its length sufficient to accommodate a fixation screw,” is supported throughout the specification, including at page 2, lines 13-14 (“said one or more bone blocks is cut to provide a groove sufficient to accommodate a fixation screw”); and at page 4, last 4 lines to page 5, lines 1-3 (“To facilitate placement of a fixation screw, the dowels are preferably machined down the **length** of the bone block to form radius cuts 115, 125. The radius cuts 115, 125 aid in the attachment of the graft to recipient bone because they provide a groove to position a fixation screw, which results in increased surface area at the contact between the bone block and the screw. The radius cuts 115, 125 provide the additional advantage of increasing the pull out loads of the bone block, as well as filling of “dead” space in the tunnel.”); emphasis added in bold. The amendments to claims 4, 8, and 9 merely clarify the language of the claims and conform the claims to the style of claim 1.

Further, the newly added claims also do not contain new matter. Claim 31, which recites that the graft is “configured such that it may be utilized “bi-directionally,” is

supported in the second paragraph of page 8 (“Shown in Figure 8 is a further embodiment **800** of the subject BTB that is especially adapted for implantation during knee surgery, wherein the implantation and securement of the BTB is bi-directional.”). Claim 32, which recites that the “graft is processed to minimize the level of antigenic agents or potentially pathogenic agents,” is supported on page 9, lines 16-18 (“Xenograft implants may further require treatments to minimize the level of antigenic agents and/or potentially pathogenic agents present in the graft”). Claim 33, which recites “one or both of said bone blocks further comprises a graft manipulation hole,” is supported throughout the specification, including at page 8, lines 29-31 (“Accordingly, BTB embodiment **800** is provided with preformed graft manipulation holes **852** and **854** for receiving a suture and/or graft insertion tools.”). Claim 34, which recites that the dowel shaped bone block is a “cylindrical dowel” is supported throughout the specification, including at Figs. 1 and 3 (showing dowels with cylindrical cross-sections) and at page 6, lines 7-9 (“The extracted bone blocks **330**, **340**, and **350** are generally shaped like a plug or dowel and are preferably further shaped by machining through conventional methods known in the art.”). Claim 35, which recites that the cylindrical dowel has a diameter of “diameter of 9 mm, 10 mm, 11 mm, or 12 mm,” is supported throughout the specification, including at page 6, lines 12-13 (“Preferred dimensions for the dowels include 8 mm, 9 mm, 10 mm, 11 mm, and 12 mm in diameter.”) Claim 36, which recites that the dowel shaped bone blocks are tapered dowels, is supported by page 5, lines 13-14 (“Figure 2B shows another version of the BTB, wherein the bone blocks are pre-shaped into dowels with tapered ends.”). Claim 37, which recites that the bone block has a “square cross-section,” is also supported throughout the specification, including at Example 1, steps 6-7 (“6. With a saw, cut and square the sides of the tibia bone block even with the tendon. 7. With a saw cut and square the patella block on three sides (if quadriceps tendon is still attached square off only the medial and lateral sides).”) Claim 38, which is directed to a xenogenic bone-tendon-bone graft wherein “said first bone block is derived from a patella, said second bone block is derived from a tibia, and said tendon is a patellar tendon,” is supported throughout the specification, including at page 9, lines 8-12 (“A BTB obtained from a pig knee according to the disclosed method is shown in FIGS. 9A, 9B and 9C. The BTB is traditionally cut and not pre-shaped. FIG. 9A shows a posterior view of the BTB graft generally indicated

at 900 comprising a section of tibia bone 901 bone, and a section of patella bone 902 connected together by a patella tendon 903. FIG. 9B shows the same graft from an anterior perspective showing the tibia bone 901, patella bone 902 and tendon 903. FIG. 9C is a picture of the BTB of FIG. 9A from the side to demonstrate the thickness of the tendon 903 between the tibia bone 901 and patella bone 902.”). Claim 39, which recites that the xenogenic bone graft of claim 38 is of “porcine” origin is supported throughout the specification, including at page 9, lines 8-12 (cited above); page 10, lines 12-13 (“the anatomical status of non-human knees (e.g., porcine) provide a viable alternative source for procuring BTBs”); and at FIGs 9A-9C (depicting a porcine bone-tendon-bone graft comprising a patellar tendon naturally connected to its patella at one end and to its tibia at the other). Claim 40, which recites that the xenogenic bone graft of claim 38 is of “porcine” origin is supported throughout the specification, including at page 10, lines 15-16 (“other xenografts sources can be used as well including, but not limited to , bovine, equine and other ruminant animals.”).

For all these reasons, the amendments to the claims are fully supported by the specification as originally filed and do not add new matter.

Election/Restrictions

In response to the Examiner’s restriction/election requirement of May 16, 2003, the Applicants previously elected with traverse Group I, Species II. In the present Office Action, the Examiner has made final the restriction/election requirement. Claims 12-26, 29 and 30 have therefore been canceled without prejudice to the filing of one or more continuing applications.

Oath/Declaration

In response to the Examiner’s objection to the oath/declaration, the Applicants respectfully disagree that a new oath/declaration is mandated. The declaration correctly identifies the application serial number from which priority is expressly claimed. That serial number has an inherent filing date associated with it. The fact that the Applicants’ declaration contained a typographical error in the filing date is an

inconsequential error. Moreover, paragraph 1 of the specification which is the subject of the declaration correctly identifies the filing date. Consistent with the Applicants' position, the Patent Office issued a filing receipt correctly indicating both the application serial number and its inherent filing date. Moreover, the published application also utilized the correctly claimed serial number to correctly indicate the claim of priority.

Thus, the Applicants' claim of priority to Serial No. 09/481,319, which has an inherent filing date of record does not mandate the correction of an inconsequential error in the declaration.

Objection to Specification

The Examiner objected to the disclosure alleging that the detailed description of the drawings did not describe figures 2A-2C. Applicants, therefore, have amended the detailed description to add descriptions for figures 2A-2C. This amendment does not add new matter. The amendment finds support in the detailed disclosure of the invention on page 5, lines 10-22.

Additionally, the Examiner objected to the form of the abstract. The Applicants believe that the abstract as amended overcomes the Examiner's objections.

Summary of the Bases for Rejection

Claim 27 is rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,951,560 ("Simon").

Claims 1,3, 7-11 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Pub. No. 2002/0165611A1 ("Enzerink") in view U.S. Patent No. 5,961,520 ("Beck").

Claims 2 and 6 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Pub. No. 2002/0165611A1 ("Enzerink") in view of U.S. Patent No. 5,961,520 ("Beck"), and further in view of U.S. Patent No. 6,210,440 B1 ("Stone").

Claims 4 and 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pub. No. 2002/0165611A1 ("Enzerink") in view of Beck, Jr. et al U.S. Patent No. 5,961,520, and further in view of U.S. Patent No. 5,951,560 ("Simon").

Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,951,560 (“Simon”) in view of U.S. Patent No. 6,210,440 B1 (“Stone”).

The Applicants will address each of these bases for rejection in Sections I-V, respectively, which follow.

I. 35 U.S.C. §102(e)

Applicants have canceled claim 27 in the interest of clear and expeditious examination. Therefore, the rejection of claim 27 under U.S.C. §102(e) is moot.

II. 35 U.S.C. §103(a) Enzerink in view of Beck

Claims 1, 3, 7-11 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Pub. No. 2002/0165611A1 (“Enzerink”) in view U.S. Patent No. 5,961,520 (“Beck”). Claims 3, 7, and 10-11 have been cancelled. Therefore, the rejections based on those claims has been rendered moot. Only claims 1 and 8-9 remain subject to this basis for rejection.

Claims 1 and 8-9 as amended would not have been obvious over Enzerink in view of Beck. Applicants have amended claim 1 by adding the phrase “naturally occurring tendon-to-bone attachment.” As amended herein, claim 1 is drawn to an implantable structure comprising a first bone block, a second bone block and a tendon wherein the ends of the tendon are attached by a “naturally occurring tendon-to-bone attachment” on the first bone block and the second bone block. The term “naturally occurring” is used throughout the biological arts to refer to the form found in nature. Specifically, the Applicants searched the USPTO’s patent database for the term “naturally occurring” and found the term used in 60,977 U.S. patents since January 1, 1976. Hence, the term “naturally occurring” is a common well-known term in the art and in the English language.

During the Applicant’s search, the Applicants become aware of the use of the term “naturally occurring” as used in the context of bone in U.S. Pat. No. 5,067,962 (“Campbell”), cited in an IDS filed herewith. For example, Campbell uses the phrase “by a naturally occurring ligament-to-bone attachment” in the same context as the Applicants wherein the tendon or ligament attachment to the bone is “naturally occurring”:

The bovine joint 13 includes a first bone 14, a second bone 15, and a bovine ligament 16, the bovine ligament 16 being chosen so that its size and strength are sufficient for human weight bearing application, and it is removed in such a manner to leave intact the **naturally occurring ligament-to-bone attachment**. A first end portion 17 of the bovine ligament 16 (FIG. 1) is attached to the first bone 14 at a first **naturally occurring ligament-to-bone attachment** site (an attachment site 18) and a second end portion 19 of the bovine ligament 16 is attached to the second bone 15 at a second **naturally occurring ligament-to-bone attachment** site (an attachment site 20).

[Exhibit A: Campbell at col. 2, line 61 to col. 3, line 5; emphasis added in bold.]

Thus, in the present context, the term “naturally occurring tendon-to-bone attachment” is recognized in the art to mean that the tendon is attached to the bone block in a “naturally occurring” manner (*i.e.*, as found in nature) and not artificially such as by a staple, stitch or screw.

The Patent Office contends that Enzerink “discloses a xenograph bone tendon bone graft comprising a plurality of bone plugs (20 & 22), a tendon (12) attached to each end of the bone plugs and a fixation screw (66). The Patent Office acknowledges that Enzerink does not disclose a groove capable of accommodating a screw. Additionally, the Patent Office contends that Beck discloses an anchoring member made of bone, having a threaded profiled groove, the threaded profile helping in the insertion of the threaded member for the purpose of helping the fixation screw attach the plug with the bone tunnel.

However, one of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in the prior art. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. Nowhere do Enzerink or Beck either alone or in combination, teach a xenograph bone-tendon-bone graft with a “**naturally occurring tendon-to-bone attachment**.” Enzerink teaches the use of **artificial or mechanical means** (*i.e.*, sutures) for attaching separate semitendinosus tendons to the separate bone plugs. See Enzerink

Figures 1-14. Similarly, Beck teaches that the tendons are wrapped around an endosteal anchoring device.

Specifically, Enzerink discloses that an allograft replacement ligament may be prepared using patella tendons which are “harvested with bone plugs (not shown).” [Enzerink at page 3, ¶ 43 lines 1-3.] However, Enzerink fails to disclose or suggest that the harvested tendons and the harvested bone plugs are attached to one another (*i.e.*, have naturally occurring tendon-to-bone attachments). *See* Enzerink et al., ¶43. Rather, Enzerink discloses throughout the specification that the bone plugs are attached to the tendons via sutures. In fact, the very next sentence of ¶43 of Enzerink states that “Preparation of these replacement ligaments includes pre-attached sutures to facilitate subsequent insertion,” which teaches away from the Applicants’ use of a unitary, **naturally** occurring bone-tendon-bone attachment. [Enzerink, ¶43, lines 4-7.]. Further, each of FIGs 1-14 of Enzerink depicts isolated bone blocks that are **mechanically** attached to a tendon via sutures. Thus, Enzerink’s unclear statement cannot be said to teach the use of naturally occurring tendon-to-bone attachments to one of ordinary skill in the art. *See Mobil Oil Corp. v. W. R. Grace & Co.*, 367 F. Supp. 207, 256 (D. Conn. 1973) (“A patent which is obscure and ambiguous in its teaching is too indefinite to be utilized as a reference.”).

For these reasons, independent claim 1 and dependent claims 8-9 would not have been rendered obvious over U.S. Pub. No. 2002/0165611A1 (“Enzerink”) in view of U.S. Patent No. 5,961,520 (“Beck”).

Additionally, Applicants note that U.S. Pat. No. 5,067,962 (“Campbell”) and U.S. Pat. No. 5,092,887 (“Gendler”) which are now cited in an IDS co-filed herewith, do not themselves render the present claims as amended unpatentable. Neither Campbell nor Gendler disclose a xenogenic bone-tendon-bone graft useful in orthopedic surgery comprising one or more bone blocks and a tendon attached by a naturally occurring tendon-to-bone attachment to said one or more bone blocks, wherein said one or more bone blocks is cut to provide a groove sufficient to accommodate a fixation screw. Campbell discloses only a naturally occurring bone-ligament-bone attachment. Gendler discloses only artificial ligaments and tendons. Gendler does mention the term “natural,” but only in the context of natural **repair**, *i.e.*, aiding the patient’s own natural tendon repair

process by artificially supporting the joint; **not** by employing an implant comprising a **naturally occurring bone-tendon-bone attachment**, which will itself be the replacement tendon. In fact, Gendler teaches away from the use of xenografts, stating that “xenografts have tended to be unpredictable in the long term for restoring full strength and stability to the involved joint,” and advocates artificial tendon replacement. Gendler at Column 1, lines 33-36.

III. 35 U.S.C. §103(a) Enzerink et al in view of Beck, Jr. et al, and further in view of Stone et al.

Claims 2 and 6 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Pub. No. 2002/0165611A1 (“Enzerink”) in view of U.S. Patent No. 5,961,520 (“Beck”), and further in view of U.S. Patent No. 6,210,440 B1 (“Stone”). Claim 6 has been canceled. Therefore, the rejection of claim 6 is moot and only claim 2 remains subject to this basis for rejection.

Claim 2 would not have been rendered obvious by the references in view of the amendments to parent claim 1. Specifically, independent claim 1, as amended, is directed to a xenogenic bone-tendon-bone graft useful in orthopedic surgery, with a tendon attached by a naturally occurring tendon-to-bone attachment to bone blocks having grooves sufficient to accommodate fixation screws. Dependent claim 2 is further directed to the bone graft of claim 1, wherein the graft is obtained from porcine, bovine, equine, goat, and other ruminant sources.

The Patent Office contends that Enzerink as modified by Beck discloses the invention substantially as claimed. The Patent Office, however, recognizes that Enzerink as modified by Beck does not disclose that the graft is from porcine, bovine, etc. The Patent Office contends that Stone teaches that tendons from pigs, cows, and other animals are well known to be used in the replacement of human tendons and ligaments for the purpose of being suitable for heterologous transplantation. The Patent Office contends that it would have been obvious to modify the Enzerink reference with different types of xenografts according to Stone. The Applicants respectfully disagree.

As discussed above in Section III, nowhere do Enzerink or Beck, either alone or in combination, teach a xenograph bone-tendon-bone graft with a “**naturally**

occurring tendon-to-bone attachment.” Enzerink teaches the use of tendons tied and sutured around a bone plug. *See* Enzerink Figures 1-14. Beck teaches that the tendons are wrapped around an endosteal anchoring device. Similarly, Stone does not teach such a “naturally occurring tendon-to-bone attachment.” Rather, Stone merely teaches methods of preparing xenogenic ligament grafts. Further, even assuming that the combination did suggest a xenogenic BTB, none of the references alone or in combination teach Applicants’ claimed “groove” on each if the bone blocks suitable for accommodating a fixation screw, such as an interference screw. Thus, none of the references, either alone or in combination, teaches or suggests the elements of independent claim 1. Therefore, claims 2 and 6, which incorporate these elements, would not have been unpatentable over Enzerink in view of Beck, and further in view of Stone for the same reasons. Applicants respectfully request the withdrawal of this basis for rejection.

IV. 35 U.S.C. 103(a) Enzerink et al in view of Beck, Jr. et al, and further in view of Simon et al.

Claims 4 and 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pub. No. 2002/0165611A1 (“Enzerink”) in view of U.S. Patent No. 5,961,520 (Beck), and further in view of U.S. Patent No. 5,951,560 (“Simon”). New claims 34-36, which are dependent on claim 4, correspond to claim 5, now cancelled. Thus, only claims 4 and 34-36 are subject to this basis for rejection.

Claim 4 has been amended to reflect dependency upon independent claim 1. Claim 1, as amended, of the Applicants’ invention is directed to a xenogenic bone-tendon-bone graft useful in orthopedic surgery, with a tendon attached by a naturally occurring tendon-to-bone attachment to bone blocks having grooves sufficient to accommodate fixation screws. Dependent claim 4, and new claims 34 and 35 are further directed to the bone graft of claim 1, wherein the bone blocks are shaped into a dowel (claim 4), are “cylindrical” dowels (claim 34), and have a diameter of 9 mm, 10 mm, 11 mm, or 12 mm (claim 35).

The Patent Office contends that Enzerink as modified by Beck discloses the invention substantially as claimed. The Applicants disagree for the reasons stated in

Section III *supra*. Enzerink as modified by Beck does not teach or suggest the Applicants' bone plugs shaped into dowels (claim 4).

The Patent Office next contends that Simon "discloses a plurality of bone blocks (49 & 53) shaped into a dowel or taper and attached to a tendon for the purpose of optimizing the threaded engagement of the fixation screws (10 & 30) with the bone tunnel." [Official Action at page 6.] Specifically, Simon states, "The screws 10 and 30 can also be used with substitute grafts having cylindrically-shaped bone blocks instead of the trapezoidally-shaped bone blocks illustrated in FIG. 33." [Simon at col. 5, lines 31-33.] However, in the referenced FIG. 33 of Simon, Simon depicts the use of isolated bone blocks that compress against the side of a tendon that is also positioned in a hole drilled in a patient's bone. The function of Simon's wedge-shaped screw is to **mechanically** compress a correspondingly wedge-shaped bone block against the **side** of the tendon to affix both the tendon and the bone block into the hole. Likewise, Beck depicts the use of an isolated "anchor body 23" [Beck at col. 6, line 40] to compress the **side** of the tendon against the side of the hole to mechanically affix both therein. In contrast, the Applicants' BTB graft has two bone blocks that are **naturally** attached to the **ends** of the tendon. As a result, Applicants' xenogenic bon-tissue-bone graft does not require a compression fit to confer a **mechanical** (artificial) attachment between the tendon and the bone block.

Thus, none of the references, either alone or in combination, teach the elements of independent claim 1 (*i.e.*, a bone-tendon-bone graft having a "naturally occurring bone-tendon-bone attachment"), **nor** teach or suggest the bone block of such BTBs having a groove for an interference screw. As a result, of claim 4 would not have been obvious under 35 U.S.C. §103 over Enzerink in view of Beck, further in view of Simon. Likewise, dependent claims 34-36, which include the same limitations, would not have been obvious over the cited references. Applicants respectfully request the withdrawal of this basis for rejection.

V. 35 U.S.C. 103(a) Simon et al in view of Stone et al.

Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,951,560 ("Simon") in view of U.S. Patent No. 6,210,440 B1 ("Stone"). Claim 28 has been cancelled. Therefore, this basis for rejection has been rendered moot.

CONCLUSION

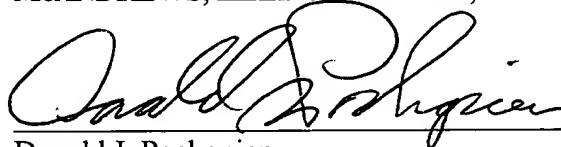
Claims 1-11 and 27-28 stand rejected. Withdrawn claims 2-26, 29-30 have been cancelled. Rejected claims 3, 5-7, 10-11, 27-28 have been cancelled in order to expedite examination. Claims 31-40 have been added by amendment herein. Accordingly, claims 1-2, 4, 8-9 and 31-40 are pending.

In view of the amendment provided herein, all bases for rejecting claim 27 under 35 U.S.C. §102(e) have been rendered moot. In view of the amendments and arguments provided herein, all bases for rejecting claims 1, 2, 4, 8-9, under 35 U.S.C. § 103(a) for alleged obviousness have been rebutted. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

Date: February 11, 2004

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